Remarks/Arguments

I. Claim Rejections under 35 USC § 112 First Paragraph

A. Claims 1-3, 5, 6, 9-13, 27,-31, and 39 are rejected under 35 USC § 112, ¶1 as failing to comply with the written description requirement. In particular, the Office Action asserts that the term "substantially free of polysomes" is not supported in the specification. Applicants note that the specification teaches the term "as free of ribosomes as possible" (Line 8, page 15) and one of ordinary skill in the art would know what is meant by "substantially free of polysomes". However, to expedite the patent prosecution, the amended claims now recite "polysome-free", which is supported by line 7, page 15. Applicants believe that one skilled artisan would appreciate that the term "polysome-free" is the same as the term "substantially free of polysomes". Accordingly, the present amendments render the rejections moot and applicants respectfully request that the rejections be withdrawn.

B. Claim 27 is rejected 35 USC § 112, ¶1 as failing to comply with the written description requirement. In particular, the Office Action admits that the phrase "means for sequestering proteins that bind to poly(A)" is supported by the specification of US Application No. 09/320, 609 which is incorporated by reference in its entirety in the present application. However, the Office Action asserts tha the phrase is not supported in the current specification. Applicants note that the exact phrase is

supported by line 2, page 11 of the present application. Accordingly, applicants respectfully request that the rejection be withdrawn.

C. Claims 1-3, 6, 9-13, 17, 19, 20 and 27-40 are rejected under 35 USC § 112, ¶1 as not being enabling for all mammalian cell extracts. However, the Office Action concedes that the specification is enabling for an S100 HeLa cell cytoplasmic extract.

The amended claims recite "a polysome-free HeLa cell cytoplasmic extract". The Office Action recognizes that the applicants have "provided useful information regarding decapping in HeLa cells" (page 7 of the Office Action, emphasis added). In addition, the Office Action "acknowledges the fact that the instant specification provides working examples and guidance with respect to the use of HeLa cells" (page 8 of the Office Action, emphasis added).

The specification, on the other hand, points out that the "mammalian cytoplasmic extract may be derived, for example, from HeLa S3 cell, but it is not so limited, and may be preparing by clearing of robosomes and other organelles from a cytoplasmic extract from the cells." (line 28-29, page 14). In addition, the term "cell cytoplasmic extract" is defined as being inclusive of the various means of preparing a polysome-free, high-speed supernatant prepared from lysed mammalian cells. (lines 6-7, page 15). The specification further provides guidance to make a polysome-free HeLa cell cytoplasmic extract and presents S100 HeLa cell cytoplasmic extract as an example thereof.

Since HeLa S100 extract is merely a working example of polysome-free HeLa cell cytoplasmic extracts and is enabling, Applicants find no reason that the HeLa cell cytoplasmic extract is not enabling based on the teachings in the specification. Accordingly, the instant specification is enabling for "polysome-free HeLa cell cytoplasmic extract". Applicants respectfully request that the rejections be reconsidered and withdrawn.

II. Claim Rejections under 35 USC § 112, Second Paragraph

A. Claims 1-3, 5, 6, 9-13, 27-31, 38 and 39 are rejected under rejected 35 USC § 112, ¶2 as being indefinite. In particular, the Office Action asserts that the term "substantially free of polysomes" is not defined in the specification. Applicants note that the specification teaches the term "as free of ribosomes as possible" (Line 8, page 15) and one of ordinary skill in the art would know what is meant by "as free of ribosome as possible" or "substantially free of polysomes". However, to expedite the patent prosecution, the amended claims now recite "polysome-free", which is supported and defined in the specification (line 7, page 15). Applicants believe that one skilled artisan would appreciate that the term "polysome-free" is the same as the term "substantially free of polysomes". Therefore, Applicants respectfully request that the rejections be withdrawn.

B. Claims 31 and 39 are rejected under rejected 35 USC § 112, ¶2 as being indefinite. In particularly, the term "ARE" is recited without first defining the acronym. The Office Action states that it would be remedial to indicate that an ARE is an AU-rich

element. Applicants have made amendments accordingly and respectfully request that the rejections be withdrawn.

II. Claim Rejections under 35 USC § 102

Claims 17, 20, 35, 40 are rejected under 35 USC § 102(b) as being anticipated by Hellmann et al. (Hellmann *et al.*, A polypeptide which reverses cap analogue inhibition of cell-free protein synthesis, J. Biol. Chem. 257:4056-4062 (1982)).

Applicants note that the current claims recite a HeLa cell cytoplasmic extract. Hellmann et al teach a rabbit reticulocyte lysate. A rabbit reticulocyte lysate is *not* a HeLa cell extract.

Applicants further note that it has been well known in the art that the reticulocyte cell-free extract, taught by Hellmann et al., contains all the macromolecular components required for translation of exogenous RNA, which include polysomes or ribosomes. See, Merrick, Translation of Exogenous mRNAs in Reticulocyte Lysates, *Meth. Enzymol.* 101: 606 – 615 (1983); Morley & Hershey, A Fractionated Reticulocyte Lysate Retains High Efficiency for Protein Synthesis, *Biochimie.* 72:259-264 (1990). In contrast, the claimed cytoplasmic extract is polysome-free.

In light of the foregoing, it appears that Hellmann *et al.* do not teach "polysome-free HeLa cell cytoplasmic extract". Accordingly, Applicants respectfully request that the rejections be withdrawn.

Applicants believe that the present amendments place the application in condition for allowance. A Notice of Allowance is, therefore, respectfully requested. If any additional issue needs to be addressed to expedite the prosecution of this application, please feel free to call the undersigned at (310) 788-3218.

Respectfully submitted,
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